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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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| UNITED STATES OF AMERICA<br><br>Plaintiff,<br><br>v.<br><br>ABLE LABORATORIES, INC., a corporation, and MURTY VEPURI, PAUL MANNING, and MARK FENTON, Individuals,<br><br>Defendants. | Civil Action No. 91-4916 (AJL)<br><br>AGREED ORDER OF PERMANENT INJUNCTION |

Whereas, the United States of America, plaintiff herein, filed a complaint for injunction against Able Laboratories, Inc., a corporation, and Murty Vepuri, Paul Manning, and Mark Fenton, individuals;

The defendants filed an answer denying the allegations in the complaint;

The parties came before the Court by way of a conference on the day of trial;

The parties agreed to resolve this matter amicably, and for good cause shown;

The Court, by order dated March 2, 1992 required, the Food and Drug Administration ("FDA") to inspect the defendants' manufacturing facility and determine, by March 17, 1992, whether the defendants were operating the facility in compliance with the Current Good Manufacturing Practice ("CGMP") regulations for drugs, 21 C.F.R. Parts 210 and 211;

The order further required the defendants to provide FDA investigators with any available validation and certification materials by March 4, 1992, and to suspend all or any part of their operations upon notification by FDA that the agency had found CGMP violations in the course of the inspection;

The order further provided that the defendants were permanently enjoined from violating the Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§301-392 ("FD&C Act") and the implementing regulations, after FDA determined that their operation was in compliance with CGMPs;

The order further provided that the parties submit an Agreed Order of Permanent Injunction upon conclusion of the inspection; and

FDA has concluded, based on its inspection of March 4 to March 17, 1992, and based on the corrective action taken by the defendants to all deviations found in the inspection, that the defendants' manufacturing facility is operating in substantial compliance as of March 31, 1992;

IT IS, on this 8th day of April, 1992, HEREBY ORDERED, ADJUDGED, AND DECREED that:

I. This Court has jurisdiction over the subject matter herein, and has personal jurisdiction over all parties to this action.

II. The complaint for injunction states a cause of action against the defendants under the FD&C Act.

III. Mark Fenton is hereby dismissed as a defendant in this action.

IV. The defendants, Able Laboratories, Inc., a corporation, and Murty Vepuri, and Paul Manning, individuals, and each and all of their officers, agents, employees, and any and all persons in active concert or participation with them, or any of them, who have received actual notice of this order by personal service or otherwise, are hereby permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly:

A. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce any drug that is adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding for sale do not conform to, or are not operated or administered in conformity with, current good manufacturing practice, as set out in 21 C.F.R. Part 210 or 211; and

B. Violating 21 U.S.C. § 331(k) by manufacturing, processing, packing, labeling, holding, or doing any other act with respect to a drug while such drug is held for sale after shipment of one or more of its components in interstate commerce,

which act results in the drug being adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

V. The defendants' expert consultant shall review Certificates of Analysis and all laboratory records in support thereof pertaining to finished product release testing generated prior to March 17, 1992 for each lot of drug manufactured prior to March 17, 1992, and on hand at the time this order is entered, and unless FDA disapproves in writing the defendants' expert's certification within three business days, the defendants may ship each lot as to which their expert consultant has certified that the laborabory records pertaining to finished product release testing generated prior to March 17, 1992 show compliance with CGMPs related to such records, and which conforms to the specifications set forth in the Certificate of Analysis.

VI. Defendants shall recall any drug product that FDA deems was not manufactured, processed, packed, labeled, or shipped in compliance with CGMP and that FDA deems would pose a risk to public health. All costs of the recalls shall be borne by the defendants. The costs of FDA's involvement in the recalls shall be borne by the defendants in accordance with the rates specified in § VIII.

VII. During the twelve months from the date of this Order, the defendants shall provide to its employees sufficient CGMP training conducted by qualified experts to ensure that the employees can properly perform their assigned functions, and thereafter, shall continue such training with sufficient frequency to ensure that employees remain familiar with CGMP

requirements applicable to them. All training that Able relies on as evidence of compliance with this provision shall be documented.

VIII. Defendants shall permit duly authorized FDA representatives to make inspections, as FDA deems necessary, of defendants' facilities, including the buildings, pertinent equipment, finished and unfinished materials, containers and labeling, in accordance with the scope of 21 U.S.C. § 374, in order to ensure continuing compliance with the terms of this Order. Such inspection shall be authorized upon presenting a copy of this Order and appropriate credentials. Such inspection authority granted by this Order is apart from, and in addition to, FDA's authority to make inspections under 21 U.S.C. § 374.

IX. The government may petition this Court to require the defendants to reimburse FDA for the costs of any inspections or examinations pursuant to this Order that indicates a failure to comply with this Order at the rate of $45.00 per hour and fraction thereof per representative for inspectional work; $54.00 per hour and fraction thereof per representative for laboratory and analytical work; all travel expenses including tolls and $0.25 per mile; and $120.00 per diem for subsistence expenses where necessary. The defendants shall not be required to reimburse FDA for inspections that are conducted for purposes other than to evaluate compliance with this order. In addition, if the defendants violate this Order and are found in civil or criminal contempt thereof, they shall, in addition to other remedies, reimburse the plaintiff for its attorney fees,

investigational expenses, and court costs relating to such contempt proceedings.

X. Within 10 days of the date of the entry of this order, the defendants shall serve a copy of the Order upon each of their officers, agents, employees and any and all persons in active concert or participation with them. Within 30 days of the date of the entry of this order, the defendants shall provide to the FDA District Director, Newark District Office, Food and Drug Administration, 61 Main Street, West Orange, New Jersey, 07052, and to plaintiff's attorneys, an affidavit of compliance stating the fact and manner of compliance with this paragraph and identifying the names and positions of all persons upon whom this Order has been served.

XI. Defendants shall notify the District Director, Newark District Office, at least 10 days before any change in ownership or character of their business, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in defendants' corporate structure, or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this order. The defendants shall provide a copy of this Order to any successor or assignees prior to any sale, assignment or other change that may affect compliance with this order. This Order shall be binding on all successors and assigns of the defendants.

XII. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Order and for the purposes

of granting such additional relief as may be necessary or appropriate. FDA's decisions under this Order shall be reviewed, if necessary, under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A).

XIII. If within 24 months following the entry of this decree, the majority ownership of the corporate defendant, or its successors or assigns, is not vested jointly or severally in the two named individual defendants, or either of them, and the government has not initiated a court action based on alleged violations of this decree, the individual defendants, or either of them, may submit a request to FDA that FDA join in a petition for relief from this decree, and may seek such relief. If, within 60 months following the entry of this decree, the government has not initiated a court action based on alleged violations of this decree, the corporate defendant may submit a request to FDA that FDA join in a petition for relief from this decree, and may seek such relief.

XIV. Each party to this action shall bear its own costs and attorneys' fees.

Dated: 8 April 92

ALFRED J. LECHNER, JR.
United States District Judge